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JUSTICE, GINA CHIEUN YU

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte EDWARD RICHARD YUHAS[1]

Appeal 2015-007369
Application 13/655,161
Technology Center 1600

Before JEFFREY N. FREDMAN, RICHARD J. SMITH,
and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods of treating psoriasis, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

Appellant's "invention relates to a method and compositions for treating psoriasis and other similar skin disorders . . . . The method

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[1] Appellant identifies the Real Party in Interest as Anaplasi Pharmaceuticals, LLC. (App. Br. 3.)

comprises the topical administration of a composition comprising a sterol ester." (Spec. 1:4–6.)

Claims 42–54 are on appeal. Claim 42 is illustrative:

> 42. A method for treating psoriasis comprising the topical administration of an unoccluded composition to a psoriatic area of a patient at least once a day wherein the unoccluded composition is a mixture consisting of:
>
> (a) about 75 wt% to about 99 wt% of a C_{10}-C_{30} carboxylic acid cholesterol/lanosterol mixture;
>
> (b) about 0.01 wt% to about 15 wt% of a penetration enhancer selected from the group consisting of oleyl alcohol, lauryl alcohol, isopropyl myristate, oleyl oleate, levulinic acid, glycerol monooleate, methyl laurate, sorbitan monooleate, triacetin, cetyl alcohol, cetyl lactate, dimethyl isosorbide, dipropylene glycol, ethyl hexyl lactate, glycolic acid, lauramine oxide, lauryl betaine, lauryl lactate, lauryl laurate, isopropyl palmitate, myristyl alcohol, myristal lactate, octyl salicylate, oleamine oxide, oleic acid, oleyl betaine, salicylic acid, stearyl alcohol, stearyl lactate, triethanolamine triacetate and combinations thereof;
>
> (c) about 0.1 wt% to about 10 wt% of a water-insoluble film-forming/polymeric agent selected from the group consisting of polyalkenes, oleophilic copolymers of vinylpyrrolidone, acrylic copolymers, polyethylene glycol derivatives, polyolefins, polyurethanes and mixtures thereof;
>
> (d) about 0 to about 10 wt% of an antioxidant;
>
> (e) about 0 to about 10 wt% of a preservative selected from the group consisting of propyl paraben, methyl paraben, benzyl alcohol, benzalkonium chloride, tribasic calcium phosphate and phenoxyethanol;
>
> (f) about 0 to about 15 wt% of a vitamin; and
>
> (g) optionally a further additive selected from the group consisting of viscosity increasing agents selected from the group consisting of natural waxes, synthetic waxes, C_{12}-C_{60} alcohols, C_{12}-C_{60} acids, alpha-hydroxy fatty acids, polyhydroxy fatty acid esters, polyhydroxy fatty acid amides, metal ester complexes,

> fumed silicas, organoclays, polyol polyesters, glyceryl esters, polyglyceryl esters, polysiloxanes, gelling agents, hydrogenated vegetable oils, petroleum based emollients having a chain length from C_{10}-C_{100} and mixtures thereof, emulsifiers, humectants, pH adjusting agents, chelating agents, fragrances and combinations of the foregoing.

(App. Br. 17 (Claims App'x).)

The claims stand rejected as follows:

Claims 42, 43, 49, and 50–54 under 35 U.S.C. § 103(a) over Mak,[2] Zhang,[3] and Spann-Wade.[4] ("Rejection I").

Claims 44–48 under 35 U.S.C. § 103(a) over Mak, Zhang, Spann-Wade, and Szanzer[5] ("Rejection II").

DISCUSSION

Issue

Appellant does not argue the rejection of claims 44–48 (Rejection II) separately, but rather agrees that the patentability of those claims rises or falls with claim 42. (App. Br. 9.) We thus address the patentability of claims 44–48 together with the rejection of claim 42. Appellant also contends the claims stand or fall together according to the following additional groupings: claims 49 and 53; claims 43 and 50; claims 51 and 52; and claim 54. (*Id.*)

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[2] Mak et al., US 2002/0182260 A1, published Dec. 5, 2002.
[3] Zhang et al., US 2007/0196459 A1, published Aug. 23, 2007.
[4] Spann-Wade et al., US 2011/0217248 A1, published Sept. 8, 2011.
[5] Szanzer, US 2006/0172022 A1, published Aug. 3, 2006.

The issue is whether the Examiner established by a preponderance of the evidence that claims 42–54 would have been obvious over the cited art.

Findings of Fact

FF 1. Mak teaches "methods of treating inflammation of the skin and mucosal membranes by administering compositions that contain concentrated inflammation modifiers as active ingredients." (Mak Abstract.) Mak teaches "[d]isorders for which the methods are useful include . . . psoriasis." (*Id.* at ¶ 13 and claim 75.) Mak teaches "[t]he formulation will typically contain the concentrated inflammation modifier, typically in concentrations in the range from about 0.001% to 100%, preferably, from about 0.01% to about 50%." (*Id.* at ¶ 103.)

FF 2. Mak teaches concentrated inflammation modifiers obtained from wool fats or lanolin derivatives, including super sterol ester (C_{10}-C_{30} carboxylic acid cholesterol/lanosterol mixture). (*Id.* at Fig. 5d and ¶¶ 26 and 198–236; *see also id.* at claims 36 and 37; *see also* Final Act. 2 and App. Br. 9 n.1.)

FF 3. Mak teaches "[d]osage forms for the topical administration of the concentrated inflammation modifiers . . . including powders, sprays, ointments, pastes, creams, lotions, [and] gels." (Mak ¶ 106.) Mak teaches the topical compositions can be prepared by combining the inflammation modifier with conventional pharmaceutical diluents and carriers. (*Id.*) Mak teaches the composition may include an aqueous or oily base and "suitable thickening and/or gelling agents" including, among others, "cetostearyl alcohol, propylene glycol [and] polyethylene glycols." (*Id.*) Mak teaches that various additional ingredients may be included including, *inter alia*,

vegetable oils and preservatives such as benzalkonium chlorides. (*Id.* at ¶¶ 107–110.) Mak further teaches oleic acid may be included as a penetration enhancer. (*Id.* at ¶ 167.)

FF 4. Zhang teaches formulations for treating skin disorders such as psoriasis that "include a drug, a solvent vehicle, and a solidifying agent." (Zhang Abstract and ¶ 6.) Zhang identifies solidifying agents, including, among others, polyurethane, acrylic polymers, and polyvinyl pyrrolidone. (*Id.* at ¶ 57.)

FF 5. Zhang defines the "solvent vehicle" as "compositions that include both a volatile solvent system and non-volatile solvent system." (*Id.* at ¶ 32.) Zhang teaches "the volatile solvent system can including ethanol, isopropyl alcohol, water, dimethyl ether, butane, [and] propane" among other compounds. (*Id.* at ¶ 48.) According to Zhang, "[t]oo little of the volatile solvent system [in the formulation] can make it difficult to spread the formulation on the skin." (*Id.* at ¶ 49.)

FF 6. Spann-Wade teaches topical compositions for treating psoriasis that "comprise[s] a Drug and a solvent system, wherein the solvent system comprises at least two solvent alcohols . . . . Exemplary solvent systems are those for which one of the at least two solvent alcohols is polyethylene glycol, glycerin, . . . propylene glycol, ethanol, isopropanol, or a derivative thereof." (Spann-Wade Abstract; *see also id.* at ¶¶ 283–284.) Spann-Wade discloses embodiments where the compositions are "alkonal-free and have at least one of polyethylene glycol . . . or a propylene glycol." (*Id.* at ¶ 122; *see also id.* at ¶¶ 142–143.)

FF 7. Spann-Wade teaches compositions including a drug, solvent system, and other ingredients including, for instance, up to 5% of a keratolytic agent such as salicylic acid (*id.* at ¶ 236) and the polymeric film former tricontanyl PVP (*id.* at § 253). (Final Act. 5.) Spann-Wade teaches the "polymeric film former tricontanyl PVP is well known to this art and it too is available commercially. . . . The concentration of the tricontanyl PVP polymer formulated into the compositions of the invention advantageously ranges from about 1% to about 10%." (Spann-Wade ¶ 253.)

Analysis

We begin with claim construction because it is a necessary prerequisite to comparing the claims to the prior art.

The claims recite a method of administering an "unoccluded composition [that] is a mixture consisting of" certain ingredients. Because the claims use the closed transitional phrase "consisting of," which modifies the "unoccluded mixture," the claims encompass administering the unoccluded mixture with the specific ingredients recited — and those ingredients alone. *AFG Industries, Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001) ("When a claim uses . . . 'closed' transition phrases such as 'consisting of' [such claims] are understood to exclude any elements, steps or ingredients not specified in the claim."). For example, and as argued by Appellant, ingredients such as "water, ethanol and[/]or isopropanol [] are excluded from the present claims by the transition phrase

'consisting of' to describe the claimed unoccluded topical composition." (Reply Br. 6.)

The Specification defines "unoccluded" to "refer to a transdermal formulation that is applied to the skin without the use of a support, backing member, cover or otherwise associated structure. In other words, the transdermal formulation is applied to the skin in free form." (Spec. 5:12–16.) As examples, the Specification identifies gels, ointments, lotions, pastes, mousses, aerosols, and creams. (*Id.* at 18–19.)

Claims 42 and 44–48

Claim 42 is drawn to a method of administering a composition consisting of three required ingredients, and a number of other ingredients are optional.[6] The first required ingredient is "(a) about 75 wt% to about 99 wt% of a C_{10}-C_{30} carboxylic acid cholesterol/lanosterol mixture." The Specification discloses that this ingredient is commercially available as "SUPER STEROL ESTER®." (Spec. 7:7–10.) The remaining two required ingredients are in elements (b) and (c) of claim 42, which respectively recite about 0.01 to about 15 wt% of the listed "penetration enhancer[s]" and about 0.1 to about 10 wt% of the listed "film-forming/polymeric agent[s]."

The Examiner rejected claim 42 as obvious over Mak, Zhang, and Spann Wade. The Examiner finds that Mak teaches topical formulations for treating psoriasis that include Super Sterol Ester®, and that Mak indicates the formulations can contain from 0.001 to 100% of the active agent, thus

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[6] Elements (d), (e), and (f) are optional insofar as the recited range encompasses 0 wt%. Element (g) expressly states that the listed ingredients are "optionally" added.

teaching a mixture having ingredient (a) of claim 42. (Final Act. 2–3.) According to the Examiner, discovery of the optimum concentration would have only required routine experimentation of the skilled artisan. (*Id.* at 4.) The Examiner further finds that Mak teaches use of auxiliary agents (e.g., absorption enhancers, emulsifiers, and thickening agents) in the formulation, such as cetyl and stearyl alcohol, and oleic acid, thus teaching several of the penetration enhancers listed in limitation (b) of claim 42. (*Id.* at 3–4.)

The Examiner finds "[t]he differences between the present method and the Mak method are that 1) Mak teaches using polyurethane in an 'occlusive' dressing formulation; and 2) the composition used in [the claimed method] has a penetration enhancer and a film forming agent in defined concentration ranges." (*Id.* at 4.) The Examiner thus turns to Zhang and Spann-Wade. According to the Examiner, Zhang teaches non-occlusive formulations comprising polymeric agents such as polyurethane (as solidifying agents) to provide controlled release and desirable flexing and stretching. (*Id.* at 4–5.) The Examiner finds Spann-Wade teaches topical formulations for treating psoriasis that may include, among other ingredients, a drug and the film-former tricontanyl PVP (an oleophilic copolymer of vinylpyrrolidone as recited in limitation (c) of claim 42 (Spec. 11:21–22:2)) in a concentration from about 1 to about 10 wt%.[7] The Examiner reasons it would have been obvious to modify the formulation of Mak to design a composition for anti-inflammatory topical treatment with

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[7] The Examiner finds that Spann-Wade teaches including up to 5% of salicylic acid, which is one of the penetration enhancers in the claimed concentration recited in claim 42.

the specific additives of Spann-Wade for their known and expected function and because they are "conventional auxiliary components" known in the art for use in compositions for treating psoriasis. (*Id.* at 6.)

Appellant argues "the Examiner's combination improperly ignores critical teachings of the cited references." (App. Br. 10.) According to the Appellant, "the addition of Zhang and/or Spann-Wade to Mak would not lead a skilled artisan to the present claimed invention" because the solvent systems of Zhang and Spann-Wade include ingredients that are excluded from the scope of claim 42 given its closed format. (*Id.* at 11 ("the appealed claims exclude the solvent systems required by Zhang and Spann-Wade").)

Appellant's argument is persuasive with respect to Zhang. We agree that Zhang's formulation requires a volatile solvent, such as ethanol or water, which is excluded from the scope of claim 42. (FF 4–5; Reply Br. 6.) The Examiner responds that claim 42 does not exclude the *non-volatile* solvents, such as propylene glycol and polyethylene glycol, of Zhang or Spann-Wade. (Ans. 2–3.) The Examiner is correct, but the key question is whether claim 42 encompasses volatile solvents disclosed in Zhang. We are not persuaded that it does, nor has the Examiner made any findings as to that question. Instead, the Examiner responds that the volatile solvents are not critical to Zhang's formulation and that "the reference clearly teaches that either volatile or non-volatile solvent can be used." (Ans. 3 (citing Zhang Abstract).) We disagree. Upon our reading of Zhang and based on Appellant's arguments, the reference appears to clearly require *both* a non-volatile and volatile solvent. (FF 4–5; App. Br. 12.) The Examiner has not shown otherwise and, absent hindsight, we are not persuaded the skilled

person would have predictably combined Zhang's solidifying agents with Mak's formulation in a mixture that lacked a volatile solvent.

We reach a different conclusion with respect to claim 42 and the combination of Mak and Spann-Wade.[8] Spann-Wade's solvent system requires at least two solvent alcohols, and these solvent alcohols may be polyethylene glycol and propylene glycol. (FF 6–7.) Appellant acknowledges this teaching in Spann-Wade: "a topical psoriatic composition would require . . . [options a, b] or c) a combination of polyethylene glycol and propylene glycol as taught by Spann-Wade." (App. Br. 12.) Moreover, "Appellant acknowledges that the viscosity increasing agents [limitation (g)] recited in the optional Markush grouping of claim 42 could include polyethylene glycol as taught by Spann-Wade." (App. Br. 12.) As the Examiner determined, "humectants of [limitation] (g) include polyols such as propylene glycol and polyethylene glycols according to appellant's own definition in the specification." (Ans. 2 (citing Spec. ¶ 54).) Appellant contends "claim 42 do[es] not include lower alcohols such as propylene glycol." (App. Br. 12.) But this is not persuasive as propylene glycol is a well-known humectant — an optional ingredient recited in claim 42 — consistent with the Examiner's finding. Accordingly, even assuming Spann-Wade required a solvent system that includes polyethylene glycol and propylene glycol in order to incorporate Spann-Wade's film-forming polymer, those ingredients are not excluded from claim 42.

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[8] *See generally*, *In re Bush*, 296 F.2d 491, 496 (CCPA 1961) (the Board may rely on less than all of the references relied upon by Examiner).

In Appellant's Reply Brief, Appellant acknowledges that "Mak suggests Super Sterol Ester® may be useful in treating psoriasis among other inflammatory conditions . . . [but Appellant argues Mak] provides no data confirming" the drug's efficacy and suggests the condition is not well understood. (Reply Br. 4.) Appellant also argues "Mak fails to exemplify any unoccluded topical composition containing more than 50% of a therapeutic agent and a water-insoluble film-forming polymer as required by the pending claims." (*Id.* at 6.)

These arguments are unpersuasive. Rejections under Section 103 do not require "data" confirming what is taught or suggested in the references, nor is the prior art limited to what is "exemplified." *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). Insofar as Appellant is arguing the art exemplified lower concentrations of the active agent (Super Sterol Ester®) than is recited in the claims and thus supports a determination of nonobviousness (Reply Br. 5–8), the Examiner found that the skilled person would have arrived at the claimed ranges through routine optimization in view of Mak's teaching that the agent is present in a range of between 0.001 to 100%. (FF 1; Final Act. 3.) Appellant's suggestion to the contrary is untimely new argument, as is Appellant's argument that Spann-Wade is deficient because the film-forming polymer is mentioned in a section related to sunscreens. (Reply Br. 6–7.) 37 C.F.R. § 41.41(a)(2). On the merits, Appellant fails to provide evidence demonstrating that the amount of active agent was not a routinely optimizable variable, that the claimed range supports an unexpected result or other secondary consideration, because in "cases involving overlapping ranges, . . . [the

Federal Circuit and its] predecessor court have consistently held that even a slight overlap in range establishes a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003).

For the above reasons, we conclude that the Examiner established by a preponderance of the evidence that claim 42 would have been obvious over Mak and Spann-Wade.

Claims 44–48[9] have not been argued separately and therefore fall with claim 42. 37 C.F.R. § 41.37(c)(1)(iv).

Claims 49 and 53

Appellant argues the patentability of claims 49 and 53 together. (App. Br. 14.) Claims 49 and 53 are similar in that limitations (d) and (e) are no longer optional as in claim 42; at least some antioxidant and preservative must be included. (App. Br. 18–20 (Claims App'x).) Optional limitation (g) is also further limited compared to claim 42, and no longer recites a humectant. Accordingly, Appellant argues "[b]oth claims 49 and 53 exclude the use of polyethylene glycol which claim 42 includes." (App. 14.)

The Examiner responds that "the skilled artisan would have had a reasonable expectation of successfully modifying the Mak invention by combining Super Sterol Esters with the water-insoluble polymers of Zhang or Spade-Wade [sic] with non-volatile solvents like polyols." (Ans. 4.)

We are not persuaded that Mak and Zhang can be properly combined without Zhang's volatile solvent as discussed above. On the present record, we are persuaded that claims 49 and 53 exclude polyethylene glycol and

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[9] We adopt the Examiner's findings of fact and reasoning with respect to Szanzer, which are not disputed on appeal. (Final Act. 6–7; App. Br. 13.)

propylene glycol — and thus exclude the solvent system of Spann-Wade discussed above. The Examiner has not provided findings or persuasive reasoning sufficient to demonstrate that the film-forming polymer of Spann-Wade would have been predictably included in a mixture with Mak's active agent, penetration enhancer, and other ingredients without Spann-Wade's solvent system.

For these reasons, we conclude the Examiner did not establish by a preponderance of the evidence that claims 49 and 53 would have been obvious over Mak, Zhang, and Spann-Wade.

Claims 43 and 50

Claims 43 and 50 both depend from claim 42 and each requires an unoccluded mixture where the film-forming polymer of limitation (c) is polyurethane. (App. Br. 18–20 (Claims App'x).) The Examiner relied on Zhang for teaching of polyurethane as a film-former in an unoccluded mixture. (Final Act. 4–5; FF 4.) But because we are not persuaded that Zhang's polyurethane film former would have been predictably combined with Mak's formulation to produce a composition within the scope of claim 42 (i.e., that excludes Zhang's volatile solvents), we reverse the Examiner's rejection of claims 43 and 50.

Claims 51 and 52

Appellant's argument that it would not be obvious to use hydrogenated vegetable oils as in the compositions of claim 51 or 52 because "neither Mak nor a combined reading of Mak, Zhang, and Spann-Wade teaches the specific use of 'hydrogenated vegetable oil' as a viscosity

increasing agent" (App. Br. 15) is unpersuasive for the reasons explained by the Examiner. (Ans. 4–5.)

We nevertheless reverse the rejection of claims 51 and 52 based on the dependency of those claims from claims 49 and 50 respectively.

Claim 54

We reverse the rejection of claim 54 for the reasons above and based on its dependency from claim 53.

SUMMARY

We affirm the rejection of claim 42 under 35 U.S.C. § 103(a) over Mak and Spann-Wade.

We affirm the rejection of claims 44–48 under 35 U.S.C. § 103(a) over Mak, Spann-Wade, and Szanzer.

We reverse the rejection of claims 43 and 49–54.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART